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| 09/555,971 | 11/14/2000 | Ivo Glynne Gut | 147-201P | 8231 |

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EXAMINER

LU, FRANK WEI MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,971

Applicant(s)

GUT ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 9, 10 and 14-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of species protein-substrate or protein-protein interaction (Group A in page 2 of previous office action mailed on September 30, 2002, claims 3 and 4) and species that the probes are generated as partial libraries having different mass and/or charge tags (Group B in page 3 of previous office action mailed on September 30, 2002, claims 16 and 17) is acknowledged. The traversal is on the ground(s) that: (1) "[A]pplicant traverses this restriction because it does not appear that the Examiner has issued a 'restriction requirement' or has particularly explained why the claims do not relate to a single general inventive concept under PCT Rule 13.1. From Applicant's reading of the Office Action, it appears that the Examiner is only requiring an election of species and has responded accordingly. Applicant's response should, in no way, be treated as Applicant's acceptance that the subject-matter of the instant application is subject to restriction."; and (2) "[W]ith respect to the species election of Group A, Applicant submits that the election of either item 1 or item 2 of Group A will not change the starting point for the purposes of search and examination."

First, the examiner agrees with applicant's reading of the Office Action mailed on September 30, 2002 since the examiner was only requiring an election of species in previous office action. Second, after carefully consider applicant's arguments, the examiner agrees to withdraw species election for (1) protein-substrate or protein-protein interaction (claims 3 and 4) and (2) protein-nucleic acid interaction (claims 3 and 5) (see page 2 of previous office action mailed on September 30, 2002) and combine claims 3-5 together. Third, since applicant does not

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argue species election for (1) the probes are generated by means of combinatorial solid phase synthesis (claims 11-13) and (2) the probes are generated as partial libraries having different mass and/or charge tags (claims 16 and 17), this election has been treated as an election without traverse. Therefore, this election is made FINAL and claims 1-10 and 14-20 will be examined.

Information Disclosure Statement

2. The examiner notes that the specification (pages 19-21) has listing of references. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Sequence Listing

3. The paper and CRF copy of the sequence listing filed on April 7, 2003 have been entered. Now the CRF copy is good technically and has been entered into database.

Specification

4. The disclosure is objected to because of the following informalities: (1) notes that Figure 1 contains P1 to P14, there is no description of P1 to P14; and (2) although Figure 4 describes to calculate mass spectrum of a PNA library using computer program MASP from Dr. Christoph

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Steinbeck, from the specification, it is unclear what is the computer program MASP and how the public can obtain information of computer program MASP.

Appropriate correction is required.

Claim Objections

5. Since claims 9 and 16-18 are multiple dependent claims which depend from another multiple dependent claim 6 and claims 10, 14, and 15 are dependent claims of claim 9, claims 9, 10, and 14-18 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 9, 10, and 14-18 will not be further treated on the merits.
6. Claim 1 is objected to because of the following informality: "Method" in preamble should be "A method" in order to correspond to preambles in claims 19 and 20.
7. Claims 2-8 are objected to because of the following informality: "Method" should be "the method".
8. Claims 1, 19, and 20 are objected to because of the following informalities: (1) the phrase "a nucleic acid molecule" in preamble should be "nucleic acid molecules" since the content of the claim uses "nucleic acid molecules" and does not use "nucleic acid molecule"; (2) the word "were" in step (b) should be "are" in order to keep the same English tense in steps (a) to (e) ; (3) because there is no step related to attachment of a specially hybridized probe, it is unclear that "a specifically hybridized probe" in step c) and one of a set of probes in step (a) of claim 1 or one of a test set of probes in step (a) of claims 19 and 20 are the same or not . If "a specifically

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hybridized probe” in step c) and one of a set of probes in step (a) of claim 1 or one of a test set of probes in step (a) of claims 19 and 20 are the same, the examiner suggests that applicant changes “a specifically hybridized probe” to “the probes that are hybridized” in order to correspond to “the probes that are not hybridized” in step (b) of the claims; and (4) the examiner suggests that applicant changes the phrase “determination of the nucleic acid molecules by means of the probes hybridized to them” in step (e) to “detection of the nucleotide sequence in the nucleic acid molecules by means of the probes hybridized to the nucleotide sequence” in order to correspond to the goal of the methods (preambles) in claims 1, 19, and 20.

9. Claim 3 is objected to because of the following informalities: (1) “an NH_2 ” should be “a NH_2 ”; (2) it is unclear “a support” in claim 2 and “the probe supports” in claim 3 are the same or not. If “a support” in claim 2 and “the probe supports” in claim 3 are the same, the examiner suggests that applicant changes the phrase “means of coating the surface of the probe supports” to “means of coating the surface of the support”; and (3) the examiner suggests that applicant changes the phrase “a protein-substrate, protein-protein” in last line of the claim to “a protein-substrate interaction or a protein-protein interaction” in order to characterize the claim much better.

10. Claim 4 is objected to because of the following informality: the examiner suggests that applicant changes the phrase “the protein-substrate interaction is a biotin-streptavidin bond” to “the protein-substrate interaction is by a biotin-streptavidin bond” in order to make a better sentence.

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11. Claim 5 is objected to because of the following informality: the examiner suggests that applicant changes the phrase "the protein-nucleic acid interaction is a Gene32-nucleic acid bond" to "the protein-nucleic acid interaction is by a Gene32-nucleic acid bond" in order to make a better sentence.
12. Claim 7 is objected to because of the following informality: the examiner suggests that applicant deletes the phrase "at the same time" in order to make a better sentence.
13. Claim 8 is objected to because of the following informality: the examiner suggests that applicant deletes the word "moreover" in order to make a better sentence.
14. Claim 19 is objected to because of the following informality: the examiner suggests that applicant changes the phrase "are generates" in step (a) to "are generated".
15. Claim 20 is objected to because of the following informalities: (1) "an NH₂" should be "a NH₂"; (2) it is unclear "a support" and "the probe supports" in step (b) are the same or not. If "a support" and "the probe supports" in step (b) are the same, the examiner suggests that applicant changes the phrase "means of coating the surface of the probe supports" to "means of coating the surface of the support"; and (3) the examiner suggests that applicant changes the phrase "a protein-substrate, protein-protein" in step (b) to "a protein-substrate interaction or a protein-protein interaction" in order to characterize the claim much better.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 1-8, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claims 2-8 are dependent on claim 1.
18. Claims 1, 19, and 20 are rejected as vague and indefinite in view of steps (a) to (d) because it is unclear that “the hybridized probes” in step (d) are probes that are inside of the nucleic acid-probe complexes and are not released from the nucleic acid-probe complexes or are probes that have released from the nucleic acid-probe complexes. If “the hybridized probes” in step (d) are probes that have released from the nucleic acid-probe complexes, the examiner suggests that applicant changes “the hybridized probes” to “the probes that are released from step (c)”. Please clarify.
19. Claim 2 recites the limitation “the surface of a support” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no “a surface of a support” in claim 1. The examiner suggests that applicant changes “the surface of a support” to “a surface of a support”.
20. Claim 20 recites the limitation “the surface of a support” in step (b) of the claim. There is insufficient antecedent basis for this limitation in the claim since no “a surface of a support” appears before “the surface of a support” in the claim. The examiner suggests that applicant changes “the surface of a support” to “a surface of a support”.

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Conclusion

21. No claim is allowed.

22. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.



Frank Lu
May 30, 2003